REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 5, 9, 32, and 35 have been amended, claims 7 and 34 have been canceled, and new claims 36-43 have been added. Support for new claims 36-43 can be found in the originally filed claims and throughout the specification. No new matter has been added by these amendments.

Claims 1-6, 8-12, 32, 33, and 35-43 are currently pending. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §112 Rejections

Claims 1, 2, 9-12, and 33 stand rejected under 35 U.S.C. §112, first paragraph, as the Examiner asserted that those claims fail to comply with the written description requirement. This rejection is respectfully traversed.

The issue at hand is whether a person skilled in the art at the time the present application was filed would realize that the inventors had possession of the claimed invention. The Examiner asserted that the specification fails to describe a representative number of species of fragments by their complete structure or other identifying characteristics. Applicants submit that this rejection cannot be maintained for the following reasons.

In *The Regents of the University of California v. Eli Lily & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed Cir. 1997), the Federal Circuit, quoting *Fiers v. Revel*, 984 F.2d 1171, 25 USPQ2d 1606, stated the following:

> "An adequate written description of a DNA... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention'."

Thus, the Federal Circuit concluded in the *Regents of the University of California v Eli Lilly & Co.* case that a claim reciting a microorganisms containing human insulin cDNA did not fulfill the written description requirement when the specification merely included a statement that the invention included human insulin.

In contrast, the present specification does not merely include a statement that fragments of the isolated nucleotide sequence obtained from the 5' sequence of the murine villin gene are

included in the invention. As set forth in greater detail below, scientific experiments and results are, in fact, provided in the specification. Hence, the present invention provides more than a mere wish or plan for obtaining the claimed fragments.

Specifically, a DNA sequence of a murine villin promoter is exemplified in Figure 6; several different constructs containing fragments are exemplified, for example, at pages 19 - 21 and in Figure 3; and targeted expression of a reporter gene (β-gal) using different fragments of the mouse villin gene is set forth in Figure 7. Thus, structural properties are defined in the present specification for fragments of the mouse villin gene.

Moreover, the results of these experiments are discussed in detail on pages 21 to 25 of the specification, as well as in originally filed claim 1. Applicants described the ability of fragments from the 5' sequence of the murine villin gene to effect transcription in several different cell types, as well as in transgenic mice. Thus, Applicants were in possession of a number of different fragments of the 5' sequence of the murine villin gene that were able to promote transcription.

Specifically, Applicants' disclosure demonstrates the following: (1) the four DNase I-hypersensitive sites together with the first intron are necessary to promote efficient transcription in cells of intestinal origin; (2) the intestinal-specific hypersensitive site HS II contains a major element that confers intestinal activity; (3) the hypersensitive sites HS III and HS IV also contain a major element that confers intestinal activity; (4) the regulatory elements that lie within 100 bp of the transcription initiation site were sufficient to promote transcription in cultured cells; and (5) the absence of the first intron in combination with the lack of intestine-specific HS IV was able to promote transcription in a kidney cell line, thereby suggesting that negative elements confer repression in kidney transcription are confined in these elements. Thus, the instant disclosure clearly demonstrates that the inventors had possession of the claimed fragments, particularly with respect to both functional and structural properties.

Moreover, the claims recite functionality of the fragments and are not directed toward any fragment within the 5' sequence of a murine villin gene. That is, the claims recite that the fragments have "cis-regulatory activity that promotes transcription and tissue-specific expression of the murine villin gene." The Examiner has seemingly ignored both the structural and functional limitations in the claims when maintaining this rejection. Applicants submit that the

structural and functional limitations satisfy the written description requirement according to the Federal Circuit's reasoning in *The Regents of the University of California v. Eli Lilly & Co., supra.*

Since the present specification discloses both structural and functional properties of the claimed fragments, and since the claims contain both structural and functional limitations of the claimed fragments, it is apparent that Applicants were in possession of the claimed invention at the time of filing the instant application. Therefore, Applicants respectfully request that the rejection of claims 1, 2, 9-12, and 33 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 9, 32, 34, and 35 stand rejected under 35 U.S.C. §112, second paragraph, as the Examiner asserted that those claims are indefinite for failing to particularly point out and distinctly claim the subject mater that Applicant regards as the invention.

Without acquiescing to the Examiner's rejection, claim 34 has been cancelled. Claims 9, 32 and 35 have been amended for further clarification. In view of these amendments, Applicants respectfully request that the rejection of claims 9, 32, and 35 under 35 U.S.C. §112, second paragraph, be withdrawn, and submit that the rejection of claim 34 under 35 U.S.C. §112, second paragraph, is moot.

Double Patenting Objection

Claims 7 and 34 are objected to under 37 CFR §1.75 as being a substantial duplicate of claim 3. Without acquiescing to the Examiner's objection, claims 7 and 34 have been cancelled. Therefore, Applicants submit that the objection to claims 7 and 34 under 37 CFR §1.75 for double patenting is moot.

Claim Objections

Claim 35 is objected to under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 35 has been amended to be an independent claim. In view of this amendment, Applicants respectfully submit that the objection to claim 35 is moot.

CONCLUSION

From the foregoing, favorable action in the form of a Notice of Allowance is respectfully requested. Enclosed is a $694 check ($264 for excess claim fees and $430 for a Petition for Two-Month Extension of Time fee). Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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